2. CLARIFICATIONS ON THE METHODOLOGY, RISK CHARACTERIZATION, AND OTHER ISSUES FOR DEVELOPING CRITERIA

2.1 IDENTIFYING THE POPULATION SUBGROUP THAT THE AWQC SHOULD PROTECT

Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities. For each pollutant, chronic criteria are derived to reflect long-term consumption of food and water. An important decision to make when setting AWQC is the choice of the particular population to protect. For instance, criteria could be set to protect those individuals who have average or "typical" exposures, or the criteria could be set so that they offer greater protection to those individuals who are more highly exposed. EPA has selected default parameter values that are representative of several defined populations: adults in the general population; sport (recreational) fishers; subsistence fishers; women of childbearing age (defined as ages 15-44); and children (up to the age of 14). In deciding on default parameter values, EPA is aware that multiple parameters are used in combination when calculating AWQC (e.g., intake rates and body weight). EPA describes the estimated population percentiles that are represented by each of the default exposure parameter values in Section 4.

EPA's national 304(a) criteria are usually derived to protect the majority of the general population from chronic adverse health effects. EPA has used a combination of median values, mean values, and percentile estimates for the parameter value defaults to calculate its national 304(a) criteria. EPA believes that its assumptions afford an overall level of protection targeted at the high end of the general population (i.e., the target population or the criteria-basis population). EPA also believes that this is reasonably conservative and appropriate to meet the goals of the CWA and the 304(a) criteria program. EPA considers that its target protection goal is satisfied if the population as a whole will be adequately protected by the human health criteria when the criteria are met in ambient water. However, associating the derived criteria with a specific population percentile is far more difficult, and such a quantitative descriptor typically requires detailed distributional exposure and dose information. EPA's *Guidelines For Exposure Assessment* (USEPA, 1992) describes the extreme difficulty in making accurate estimates of exposures and indicates that uncertainties at the more extreme ends of the distribution increase greatly. On quantifying population exposures/risks, the guidelines specifically state:

> *In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose-response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate estimates of real (or actuarial) cases of disease. The estimate's value lies in framing*

hypothetical risk in an understandable way rather than in any literal interpretation of the term "cases."

Although it is not possible to subject the estimates to such a rigorous analysis (say, for example, to determine what criterion value provides protection of exactly the 90th percentile of the population), EPA believes that the combination of parameter value assumptions achieves its target goal, without being inordinately conservative. The standard assumptions made for the national 304(a) criteria are as follows. The assumed body weight value used is an arithmetic mean, as are the RSC intake estimates of other exposures (e.g., non-fish dietary), when data are available. The BAF component data (e.g., for lipid values, for particulate and dissolved organic carbon) are based on median (i.e., 50th percentile) values. The drinking water intake values are approximately 90th percentile estimates and fish intake values are 90th percentile estimates. EPA believes the use of these values will result in 304(a) criteria that are protective of a majority of the population; this is EPA's goal.

However, EPA also strongly believes that States and authorized Tribes should have the flexibility to develop criteria, on a site-specific basis, that provide additional protection appropriate for highly exposed populations. EPA is aware that exposure patterns in general, and fish consumption in particular, vary substantially. EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national 304(a) criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions.

EPA has provided recommended default intake rates for various population groups for State and Tribal consideration. EPA does not intend for these alternative default values to be prescriptive. EPA strongly emphasizes its preference that States and Tribes use local or regional data over EPA's defaults, if they so choose, as being more representative of their population groups of concern.

In the course of updating the 2000 Human Health Methodology, EPA received some questions regarding the population groups for which the criteria would be developed. EPA does not intend to derive multiple 304(a) criteria for all subpopulation groups for every chemical. As stated above, criteria that address chronic adverse health effects are most applicable to the CWA Section 304(a) criteria program and the chemicals evaluated for this program. If EPA determined that pregnant women/fetuses or young children were the target population (or criteria basis population) of a chemical's RfD or POD/UF, then the 304(a) criteria would be developed using exposure parameters for that subgroup. This would only be relevant for acute or subchronic toxicity situations. This does not conflict with the fact that chronic health effects potentially reflect a person's exposure during both childhood and adult years.

For RfD-based and POD/UF-based chemicals, EPA's policy is that, in general, the RfD (or POD/UF) should not be exceeded and the exposure assumptions used should reflect the population of concern. It is recommended that when a State or authorized Tribe sets a waterbody-specific AWQC, they consider the populations most exposed via water and fish. EPA's policy on cancer risk management goals is discussed in Section 2.4.

Health Risks to Children

In recognition that children have a special vulnerability to many toxic substances, EPA's Administrator directed the Agency in 1995 to explicitly and consistently take into account environmental health risks to infants and children in all risk assessments, risk characterizations, and public health standards set for the United States. In April 1997, President Clinton signed Executive Order 13045 on the protection of children from environmental health risks, which assigned a high priority to addressing risks to children. In May 1997, EPA established the Office of Children's Health Protection to ensure the implementation of the President's Executive Order. EPA has increased efforts to ensure its guidance and regulations take into account risks to children. Circumstances where risks to children should be considered in the context of the 2000 Human Health Methodology are discussed in the Section 3.2, Noncancer Effects (in terms of developmental and reproductive toxicity) and in Section 4, Exposure (for appropriate exposure intake parameters).

Details on risk characterization and the guiding principles stated above are included in EPA's March 21, 1995 policy statement and the discussion of risk characterization (USEPA, 1995) and the 1999 *Guidelines for Carcinogen Risk Assessment. Review Draft* (USEPA, 1999a) and the *Reproductive and Toxicity Risk Assessment Guidelines* of 1996 (USEPA, 1996b).

2.2 SCIENCE, SCIENCE POLICY, AND RISK MANAGEMENT

An important part of risk characterization, as described later in Section 2.7, is to make risk assessments transparent. This means that conclusions drawn from the science are identified separately from policy judgments and risk management decisions, and that the use of default values or methods, as well as the use of assumptions in risk assessments, are clearly articulated. In this Methodology, EPA has attempted to separate scientific analysis from science policy and risk management decisions for clarity. This should allow States and Tribes (who are also prospective users of this Methodology) to understand the elements of the Methodology accurately and clearly, and to easily separate out the scientific decisions from the science policy and risk management decisions. This is important so that when questions are asked regarding the scientific merit, validity, or apparent stringency or leniency of AWQC, the implementer of the criteria can clearly explain what judgments were made to develop the criterion in question and to what degree these judgments were based on science, science policy, or risk management. To some extent this process will also be displayed in future AWQC documents.

When EPA speaks of science or scientific analysis, it is referring to the extraction of data from toxicological or exposure studies and surveys with a minimum of judgment being used to

make inferences from the available evidence. For example, if EPA is describing a POD from an animal study (e.g., a LOAEL), this is usually determined as a lowest dose that produces an observable adverse effect. This would constitute a scientific determination. Judgments applying science policy, however, may enter this determination. For example, several scientists may differ in their opinion of what is adverse, and this in turn can influence the selection of a LOAEL in a given study. The use of an animal study to predict effects in a human in the absence of human data is an inherent science policy decision. The selection of specific UFs when developing an RfD is another example of science policy. In any risk assessment, a number of decision points occur where risk to humans can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among several possible inferences when conducting a risk assessment.

Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. In this Methodology, the choice of a default fish consumption rate which is protective of 90 percent of the general population is a risk management decision. The choice of an acceptable cancer risk by a State or Tribe is a risk management decision.

Many of the components in the 2000 Human Health Methodology are an amalgam of science, science policy, and/or risk management. For example, most of the default values chosen by EPA are based on examination of scientific data and application of either science policy or risk management. This includes the default assumption of 2 liters a day of drinking water; the assumption of 70 kilograms for an adult body weight; the use of default percent lipid and particulate organic carbon/dissolved organic carbon (POC/DOC) for developing national BAFs; the default fish consumption rates for the general population and sport and subsistence anglers; and the choice of a default cancer risk level. Some decisions are more grounded in science and science policy (such as the choice of default BAFs) and others are more obviously risk management decisions (such as the determination of default fish consumption rates and cancer risk levels). Throughout the 2000 Human Health Methodology, EPA has identified the kind of decision necessary to develop defaults and what the basis for the decision was. More details on the concepts of science analysis, science policy, risk management, and how they are introduced into risk assessments are included in *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983).

2.3 SETTING CRITERIA TO PROTECT AGAINST MULTIPLE EXPOSURES FROM MULTIPLE CHEMICALS (CUMULATIVE RISK)

EPA is very much aware of the complex issues and implications of cumulative risk and has endeavored to begin developing an overall approach at the Agency-wide level. Assuming that multiple exposures to multiple chemicals are additive is scientifically sound if they exhibit the same toxic endpoints and modes of action. There are numerous publications relevant to cumulative risk that can assist States and Tribes in understanding the complex issues associated with cumulative risk. These include the following:

< Durkin, P.R., R.C. Hertzberg, W. Stiteler, and M. Mumtaz. 1995. The identification and testing of interaction patterns. *Toxicol. Letters* 79:251-264.

< Hertzberg, R.C., G. Rice, and L.K. Teuschler. 1999. Methods for health risk assessment of combustion mixtures. In: *Hazardous Waste Incineration: Evaluating the Human Health and Environmental Risks*. S. Roberts, C. Teaf and J. Bean, (eds). CRC Press LLC, Boca Raton, FL. Pp. 105-148.

< Rice, G., J. Swartout, E. Brady-Roberts, D. Reisman, K. Mahaffey, and B. Lyon. 1999. Characterization of risks posed by combustor emissions. *Drug and Chem. Tox.* 22:221-240.

< USEPA. 1999. *Guidance for Conducting Health Risk Assessment of Chemical Mixtures*. *Final Draft.* Risk Assessment Forum Technical Panel. Washington, DC. NCEA-C-0148. September. Web site: http://www.epa.gov/ncea/raf/rafpub.htm

< USEPA. 1998. *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions*. (Update to EPA/600/6-90/003 *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions*). National Center for Environmental Assessment. Washington, DC. EPA-600-R-98-137. Website http://www.epa.gov/ncea/combust.htm

< USEPA. 1996. PCBs: *Cancer Dose-Response Assessment and Application to Environmental Mixtures*. National Center for Environmental Assessment. Washington, DC. EPA/600/P-96/001F.

< USEPA. 1993. *Review Draft Addendum to the Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions*. Office of Health and Environmental Assessment, Office of Research and Development. Washington, DC. EPA/600/AP-93/003. November.

< USEPA. 1993. *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons*. Office of Research and Development. Washington, DC. EPA/600/R-93/089. July.

< USEPA. 1990. *Technical Support Document on Health Risk Assessment of Chemical Mixtures*. Office of Research and Development. Washington, DC. EPA/600/8/90/064. August.

< USEPA. 1989a. *Risk Assessment Guidance for Superfund. Vol. 1. Human Health Evaluation Manual (Part A)*. Office of Emergency and Remedial Response. Washington, DC. EPA/540/1-89/002.

< USEPA. 1989b. *Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans (CDDs and CDFs) and 1989 Update*. Risk Assessment Forum. Washington, DC. EPA/625/3-89/016. March.

The Agency's program offices are also engaged in on-going discussions of the great complexities, methodological challenges, data adequacy needs and other information gaps, as well as the science policy and risk management decisions that will need to be made, as they pursue developing a sound strategy and, eventually, specific guidance for addressing cumulative risks. As a matter of internal policy, EPA is committed to refining the Methodology as advances in relevant aspects of the science improve, as part of the water quality criteria program.

2.4 CANCER RISK RANGE

For deriving 304(a) criteria or promulgating water quality criteria for States and Tribes under Section 303(c) based on the 2000 Human Health Methodology, EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population. EPA's program office guidance and regulatory actions have evolved in recent years to target a $10^{!6}$ risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a $10^{!6}$ risk level is consistent with Agency-wide practice.

EPA believes that both $10^{!6}$ and $10^{!5}$ may be acceptable for the general population and that highly exposed populations should not exceed a $10^{!4}$ risk level. States or Tribes that have adopted standards based on criteria at the $10^{!5}$ risk level can continue to do so, if the highly exposed groups would at least be protected at the $10^{!4}$ risk level. However, EPA is not automatically assuming that $10^{!5}$ will protect "the highest consumers" at the $10^{!4}$ risk level. Nor is EPA advocating that States and Tribes automatically set criteria based on assumptions for highly exposed population groups at the $10^{!4}$ risk level. The Agency is simply endeavoring to add that a specific determination should be made to ensure that highly exposed groups do not exceed a $10^{!4}$ risk level. EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either $10^{!6}$ or $10^{!5}$ protective of those groups at a $10^{!4}$ risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a $10^{!6}$ or $10^{!5}$ risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a $10^{!4}$ risk level would be exceeded, a more protective risk level should be chosen. Such determinations should be made by the State or Tribal authorities and are subject to EPA's review and approval or disapproval under Section 303(c) of the CWA.

Adoption of a $10^{!6}$ or $10^{!5}$ risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes. EPA believes that such State or Tribal decisions are consistent with Section 303(c) if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the

chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation. States and authorized Tribes also have flexibility in how they demonstrate this protectiveness and obtain such information. A State or authorized Tribe may use existing information as well as collect new information in making this determination. In addition, if a State or authorized Tribe does not believe that the 10^{-6} risk level adequately protects the exposed subpopulations, water quality criteria based on a more stringent risk level may be adopted. This discretion includes combining the 10^{-6} risk level with fish consumption rates for highly exposed population groups.

It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). (Note: Fish consumers of up to 1,750 gm/day would not exceed the 10^{-4} risk level.) If a criterion were based on high-end intake rates and the relative risk of 10^{-6}, then an average fish consumer would be protected at a cancer risk level of approximately 10^{-8}. The point is that the risks for different population groups are not the same.

2.5 MICROBIOLOGICAL AMBIENT WATER QUALITY CRITERIA

Guidance for deriving microbiological AWQC is not a part of this Methodology. In 1986, EPA published *Ambient Water Quality Criteria for Bacteria - 1986* (USEPA, 1986a), which updated and revised bacteriological criteria previously published in 1976 in *Quality Criteria for Water* (USEPA, 1976). The inclusion of guidance for deriving microbiological AWQC was considered in the 1992 national workshop that initiated the effort to revise the 1980 Methodology and was recommended by the SAB in 1993. Since that time, however, efforts separate from these Methodology revisions have addressed microbiological AWQC concerns. The purpose of this section is to briefly describe EPA's current recommendations and activities.

EPA's *Ambient Water Quality Criteria for Bacteria - 1986* recommends the use of *Escherichia coli* and enterococci rather than fecal coliforms (USEPA, 1986a). EPA's criteria recommendations are:

- Fresh water: *E. coli* not to exceed 126/100 ml or enterococci not to exceed 33/100 ml; and

- Marine water: enterococci not to exceed 35/100 ml.

These criteria should be calculated as the geometric mean based on five equally spaced samples taken over a 30-day period.

In addition, EPA recommends that States adopt a single sample maximum, based on the expected frequency of use. No sample taken should exceed this value. EPA specifies appropriate single sample maximum values in the 1986 criteria document.

Current Activities and Plans for Future Work

EPA has identified development of microbial water quality criteria as part of its strategy to control waterborne microbial disease, by controlling pathogens in waterbodies and by protecting designated uses, such as recreation and public water supplies. The program fosters an integrated approach to protect both ground-water and surface water sources. EPA plans to conduct additional monitoring for *Cryptosporidium parvum* and *E. coli*, and determine action plans in accordance with the results of this monitoring.

EPA recommends no change at this time in the stringency of its bacterial criteria for recreational waters; existing criteria and methodologies from 1986 will still apply. The recommended methods for *E. coli* and enterococci have been improved. As outlined in the *Action Plan for Beaches and Recreational Waters* (Beach Action Plan, see below), the Agency plans to conduct national studies on improving indicators together with epidemiology studies for new criteria development (USEPA, 1999b). The Agency is also planning to establish improved temporal and spatial monitoring protocols.

In the Beach Action Plan, EPA identifies a multi-year strategy for monitoring recreational water quality and communicating public health risks associated with potentially pathogen-contaminated recreational rivers, lakes, and ocean beaches. It articulates the Agency's rationale and goals in addressing specific problems and integrates all associated program, policy, and research needs and directions. The Beach Action Plan also provides information on timing, products and lead organization for each activity. These include activities and products in the areas of program development, risk communication, water quality indicator research, modeling and monitoring research, and exposure and health effects research.

Recently, EPA approved new 24-hour *E. coli* and enterococcus tests for recreational waters that may be used as an alternative to the 48-hour test (USEPA, 1997). EPA anticipates proposing these methods for inclusion in the 40 CRF 136 in the Fall of 2000. EPA has also published a video with accompanying manual on the original and newer methods for enterococci and *E. coli* (USEPA, 2000).

As part of the Beach Action Plan, EPA made the following recommendations for further Agency study:

- Future criteria development should consider the risk of diseases other than gastroenteritis. EPA intends to consider and evaluate such water-related exposure routes as inhalation and dermal absorption when addressing microbial health effects. The nature and significance of other than the classical waterborne pathogens are to some degree tied to the particular type of waste sources.

- A new set of indicator organisms may need to be developed for tropical water if it is proven that the current fecal indicators can maintain viable cell populations in the soil and water for significant periods of time in uniform tropical conditions. Some potential alternative indicators to be fully explored are coliphage, other bacteriophage, and *Clostridium perfringens*.

- Because animal sources of pathogens of concern for human infection such as *Giardia lamblia*, *Cryptosporidium parvum*, and *Escherichia coli* 0157:H7 may be waterborne or washed into water and thus become a potential source for infection, they should not be ignored in risk assessment. A likely approach would be phylogenetic differentiation; that is, indicators that are specific to, or can discriminate among, animal sources.

- EPA intends to develop additional data on secondary infection routes and infection rates from prospective epidemiology studies and outbreaks from various types of exposure (e.g., shellfish consumption, drinking water, recreational exposure).

- EPA needs to improve sampling strategies for recreational water monitoring including consideration of rainfall and pollution events to trigger sampling.

2.6 RISK CHARACTERIZATION CONSIDERATIONS

On March 21, 1995, EPA's Administrator issued the *EPA Risk Characterization Policy and Guidance* (USEPA, 1995). This policy and guidance is intended to ensure that characterization information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers, and from EPA to the public. The policy also provides the basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across EPA programs. The fundamental principles which form the basis for a risk characterization are as follows:

- Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and the use of assumptions in the risk assessment are clearly articulated.

- Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessments, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and limitations (including uncertainties) of the assessment and conclusions.

- Risk characterizations should be consistent in general format, but recognize the unique characteristics of each specific situation.

- Risk characterizations should include, at least in a qualitative sense, a discussion of how a specific risk and its context compares with similar risks. This may be accomplished by comparisons with other pollutants or situations on which the Agency has decided to act, or other situations with which the public may be familiar. The discussion should highlight the limitations of such comparisons.

- Risk characterization is a key component of risk communication, which is an interactive process involving exchange of information and expert opinion among individuals, groups, and institutions.

Additional guiding principles include:

- The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.

- The risk characterization includes a discussion of uncertainty and variability in the risk assessment.

- Well-balanced risk characterizations present conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public.

In developing the methodology presented here, EPA has closely followed the risk characterization guiding principles listed above. As States and Tribes adopt criteria using the 2000 Human Health Methodology, they are strongly encouraged to follow EPA's risk characterization guidance. There are a number of areas within the Methodology and criteria development process where risk characterization principles apply:

- Integration of cancer and noncancer assessments with exposure assessments, including bioaccumulation potential determinations, in essence, weighing the strengths and weaknesses of the risk assessment as a whole when developing a criterion.

- Selecting a fish consumption rate, either locally derived or the national default value, within the context of a target population (e.g., sensitive subpopulations) as compared to the general population.

- Presenting cancer and/or noncancer risk assessment options.

- Describing the uncertainty and variability in the hazard identification, the dose-response, and the exposure assessment.

2.7 DISCUSSION OF UNCERTAINTY

2.7.1 Observed Range of Toxicity Versus Range of Environmental Exposure

When characterizing a risk assessment, an important distinction to make is between the observed range of adverse effects (from an epidemiology or animal study) and the environmentally observed range of exposure (or anticipated human exposure) to the contaminant. In many cases, EPA intends to apply default factors to account for uncertainties or incomplete knowledge in developing RfDs or cancer risk assessments using nonlinear low-dose extrapolation to provide a margin of protection. In reality, the actual effect level and the environmental exposure levels may be separated by several orders of magnitude. The difference between the dose causing some observed response and the anticipated human exposure should be described by risk assessors and managers, especially when comparing criteria to environmental levels of a contaminant.

2.7.2 Continuum of Preferred Data/Use of Defaults

In both toxicological and exposure assessments, EPA has defined a continuum of preferred data for toxicological assessments ranging from a highest preference for chronic human data (e.g., studies that examine a long-term exposure of humans to a chemical, usually from occupational and/or residential exposure) and actual field data for many of the exposure parameter values (e.g., locally derived fish consumption rates, waterbody-specific bioaccumulation rates), to default values which are at the lower end of the preference continuum. EPA has supplied default values for all of the risk assessment parameters in the 2000 Human Health Methodology; however, it is important to note that when default values are used, the uncertainty in the final risk assessment may be higher, and the final resulting criterion may not be as applicable to local conditions, than is a risk assessment derived from human/field data. Using defaults assumes generalized conditions and may not capture the actual variability in the population (e.g., sensitive subpopulations/high-end consumers). If defaults are chosen as the basis for criteria, these inherent uncertainties should be communicated to the risk manager and the public. While this continuum is an expression of preference on the part of EPA, it does not imply in any way that any of the choices are unacceptable or scientifically indefensible.

2.7.3 Significant Figures

The number of significant figures in a numeric value is the number of certain digits plus one estimated digit. Digits should not be confused with decimal places. For example, 15.1, 0.0151, and 0.0150 all have 3 significant figures. Decimal places may have been used to maintain the correct number of significant figures, but in themselves they do not indicate significant figures (Brinker, 1984). Since the number of significant figures must include only one estimated digit, the sources of input parameters (e.g., fish consumption and water consumption rates) should be checked to determine the number of significant figures associated with data they provide. However, the original measured values may not be available to determine the number of significant figures in the input parameters. In these situations, EPA recommends utilizing the data as presented.

When developing criteria, EPA recommends rounding the number of significant figures at the end of the criterion calculation to the same number of significant figures in the least precise parameter. This is a generally accepted practice which can be found described in greater detail in APHA (1992) and Brinker (1984). The general rule is that for multiplication or division, the resulting value should not possess any more significant figures than is associated with the factor in the calculation with the least precision. When numbers are added or subtracted, the number that has the fewest decimal places, not necessarily the fewest significant figures, puts the limit on the number of places that justifiably may be carried in the sum or difference. Rounding off a number is the process of dropping one or more digits so that the value contains only those digits that are significant or necessary in subsequent computations (Brinker, 1984). The following rounding procedures are recommended: (1) if the digit 6, 7, 8, or 9 is dropped, increase the preceding digit by one unit; (2) if the digit 0, 1, 2, 3, or 4 is dropped, do not alter the preceding digit; and (3) if the digit 5 is dropped, round off the preceding digit to the nearest even number (e.g., 2.25 becomes 2.2 and 2.35 becomes 2.4) (APHA, 1992; Brinker, 1984).

EPA recommends that calculations of water quality criteria be performed without rounding of intermediate step values. The resulting criterion may be rounded to a manageable number of decimal places. However, in no case should the number of digits presented exceed the number of significant figures implied in the data and calculations performed on them. The term "intermediate step values" refers to values of the parameters in Equations 1-1 through 1-3. The final step is considered the resulting AWQC. Although AWQC are, in turn, used for purposes of establishing water quality-based effluent limits (WQBELs) in National Pollutant Discharge Elimination System (NPDES) permits, calculating total maximum daily loads (TMDLs), and applicable or relevant and appropriate requirements (ARARs) for Superfund, they are considered the final step of this Methodology and, for the purpose of this discussion, where the rounding should occur.

The determination of appropriate significant figures inevitably involves some judgment given that some of the equation parameters are adopted default exposure values. Specifically, the default drinking water intake rate of 2 L/day is a value adopted to represent a majority of the population over the course of a lifetime. Although supported by drinking water consumption survey data, this value was adopted as a policy decision and, as such, does not have to be considered in determining the parameter with the least precision. That is, the resulting AWQC need not always be reduced to one significant digit. Similarly, the 70-kg adult body weight has been adopted Agency-wide and represents a default policy decision.

The following example with a simplified AWQC equation illustrates the rule described above. The example is for hexachlorobutadiene (HCBD), which EPA used to demonstrate the 1998 draft Methodology revisions (USEPA, 1998b). The parameters that were calculated (i.e., not policy adopted values) include values with significant figures of two (the POD and RSC), three (the UF), and four (the FI and BAF). Based on the 2000 Human Health Methodology, the final criterion should be rounded to two significant figures. The bold numbers in parentheses indicate the number of significant figures and those with asterisks also indicate Agency adopted policy values.

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + (FI \cdot BAF)} \right) \qquad \text{(Equation 2-1)}$$

Example [Refer to draft HCBD document for details on the POD/UF, RSC and BAF data (EPA 822-R-98-004). Also note that the fish intake rate in this example is the revised value.]:

$$AWQC = \left(\frac{0.054(2)}{300(3)} - 1.2 \times 10^{-4}(2) \right) \times \left(\frac{70(2^*)}{2(1^*) + (0.01750(4) \times 3{,}180(4))} \right)$$

AWQC = 7.3×10^{-5} mg/L (0.073 µg/L, rounded from 7.285×10^{-2} µg/L)
* represents Agency adopted policy value

A number of the values used in the equation may result in intermediate step values that have more than four figures past the decimal place and may be carried throughout the calculation. However, carrying more than four figures past the decimal place (equivalent to the most precise parameter) is unnecessary as it has no effect on the resulting criterion value.

2.8 OTHER CONSIDERATIONS

2.8.1 Minimum Data Considerations

For many of the preceding technical areas, considerations have been presented for data quality in developing toxicological and exposure assessments. For greater detail and discussion of minimum data recommendations, the reader is referred to the specific sections in the Methodology on cancer and noncancer risk assessments (and especially to the referenced EPA risk assessment guidelines documents), exposure assessment, and bioaccumulation assessment, in addition to the TSD volumes for each.

2.8.2 Site-Specific Criterion Calculation

The 2000 Human Health Methodology allows for site-specific modifications by States and Tribes to reflect local environmental conditions and human exposure patterns. "Local" may refer to any appropriate geographic area where common aquatic environmental or exposure patterns exist. Thus "local" may signify Statewide, regional, a river reach, or an entire river.

Such site-specific criteria may be developed as long as the site-specific data, either toxicological or exposure-related, is justifiable. For example, when using a site-specific fish consumption rate, a State should use a value that represents at least the central tendency of the

population surveyed (either sport or subsistence, or both). If a site-specific fish consumption rate for sport anglers or subsistence anglers is lower than an EPA default value, it may be used in calculating AWQC. However, to justify such a level (either higher or lower than EPA defaults), the State should assemble appropriate survey data to arrive at a defensible site-specific fish consumption rate.

Such data must also be submitted to EPA for its review when approving or disapproving State or Tribal water quality standards under Section 303(c). The same conditions apply to site-specific calculations of BAF, percent fish lipid, or the RSC. In the case of deviations from toxicological values (i.e., IRIS values: verified noncancer and cancer assessments), EPA strongly recommends that the data upon which the deviation is based be presented to and approved by the Agency before a criterion is developed.

Additional guidance on site-specific modifications to the 2000 Human Health Methodology is provided in each of the three TSD volumes.

2.8.3 Organoleptic Criteria

Organoleptic criteria define concentrations of chemicals or materials which impart undesirable taste and/or odor to water. Organoleptic effects, while significant from an aesthetic standpoint, are not a significant health concern. In developing and utilizing such criteria, two factors must be appreciated: (1) the limitations of most organoleptic data; and (2) the human health significance of organoleptic properties. In the past, EPA has developed organoleptic criteria if organoleptic data were available for a specific contaminant. The 1980 AWQC National Guidelines made a clear distinction that organoleptic criteria and toxicity-based criteria are derived from completely different endpoints, and that organoleptic criteria have no demonstrated relationship to potential adverse human health effects because there is no toxicological basis. EPA acknowledges that if organoleptic effects (i.e., objectionable taste and odor) cause people to reject the water and its designated uses, then the public is effectively deprived of the natural resource. It is also possible that intense organoleptic characteristics could result in depressed fluid intake which, in turn, might lead to an indirect human health effect via decreased fluid consumption. Although EPA has developed organoleptic criteria in the past and may potentially do so in the future, this will not be a significant part of the water quality criteria program. EPA encourages the development of organoleptic criteria when States and Tribes believe they are needed. However, EPA cautions States and Tribes that the quality of organoleptic data is often significantly less than that of toxicologic data used in establishing health-based criteria. Therefore, a comprehensive evaluation of available organoleptic data should be made, and the selection of the most appropriate database for the criterion should be based on sound scientific judgment.

In 1980, EPA provided recommended criteria summary language when both types of data are available. The following format was used and is repeated here:

For comparison purposes, two approaches were used to derive criterion levels for ____. Based on available toxicity data, for the protection of public health the derived level is ____. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water the estimated level is ____. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have no demonstrated relationship to potential adverse human health effects.

Similarly, the 1980 Methodology recommended that in those instances where a level to limit toxicity cannot be derived, the following statement should be provided:

Sufficient data are not available for ____ to derive a level which would protect against the potential toxicity of this compound.

2.8.4 Criteria for Chemical Classes

The 2000 Human Health Methodology also allows for the development of a criterion for classes of chemicals, as long as a justification is provided through the analysis of mechanistic data, toxicokinetic data, structure-activity relationship data, and limited acute and chronic toxicity data. When potency differences between members of a class is great (such as in the case of chlorinated dioxins and furans), toxicity equivalency factors (TEFs) may be more appropriately developed than one class criterion.

A chemical class is defined as any group of chemical compounds which are similar in chemical structure and biological activity, and which frequently occur together in the environment usually because they are generated by the same commercial process. In criterion development, isomers should be regarded as part of a chemical class rather than as a single compound. A class criterion, therefore, is an estimate of risk/safety which applies to more than one member of a class. It involves the use of available data on one or more chemicals of a class to derive criteria for other compounds of the same class in the event that there are insufficient data available to derive compound-specific criteria. The health-based criterion may apply to the water concentration of each member of the class, or may apply to the sum of the water concentrations of the compounds within the class. Because relatively minor structural changes within the class of compounds can have pronounced effects on their biological activities, reliance on class criteria should be minimized depending on the data available.

The following guidance should also be followed when considering the development of a class criterion.

- A detailed review of the chemical and physical properties of the chemicals within the group should be made. A close relationship within the class with respect to chemical activity would suggest a similar potential to reach common biological sites within tissues. Likewise, similar lipid solubilities would suggest the possibility of comparable absorption and distribution.

- Qualitative and quantitative toxicological data for chemicals within the group should be examined. Adequate toxicological data on a number of compounds within a group provides a more reasonable basis for extrapolation to other chemicals of the same class than minimal data on one chemical or a few chemicals within the group.

- Similarities in the nature of the toxicological response to chemicals in the class provides additional support for the prediction that the response to other members of the class may be similar. In contrast, where the biological response has been shown to differ markedly on a qualitative and quantitative basis for chemicals within a class, the extrapolation of a criterion to other members is not appropriate.

- Additional support for the validity of extrapolation of a criterion to other members of a class could be provided by evidence of similar metabolic and toxicokinetic data for some members of the class.

Additional guidance is described in the *Technical Support Document on Health Risk Assessment of Chemical Mixtures* (USEPA, 1990).

2.9.5 Criteria for Essential Elements

Developing criteria for essential elements, particularly metals, must be a balancing act between toxicity and the requirement for good health. The AWQC must consider essentiality and cannot be established at levels that would result in deficiency of the element in the human population. The difference between the recommended daily allowance (RDA) and the daily doses causing a specified risk level for carcinogens or the RfDs for noncarcinogens defines the spread of daily doses within which the criterion may be derived. Because errors are inherent in defining both essential and adverse-effect levels, the criterion is derived from a dose level near the center of such dose ranges.

The process for developing criteria for essential elements should be similar to that used for any other chemical with minor modifications. The RfD represents concern for one end of the exposure spectrum (toxicity), whereas the RDA represents the other end (minimum essentiality). While the RDA and RfD values might occasionally appear to be similar in magnitude to one another, it does not imply incompatibility of the two methodological approaches, nor does it imply inaccuracy or error in either calculation.

2.9 REFERENCES

APHA. American Public Health Association. 1992. *Standard Methods: For the Examination of Water and Wastewater.* 18th Edition. Prepared and published jointly by: American Public Health Association, American Water Works Association, and Water Environment Federation. Washington, DC.

Brinker, R.C. 1984. *Elementary Surveying.* 7th Edition. Cliff Robichaud and Robert Greiner, Eds. Harper and Row Publishers, Inc. New York, NY.

NRC (National Research Council). 1983. *Risk Assessment in the Federal Government: Managing the Process.* National Academy Press. Washington, DC.

USEPA (U.S. Environmental Protection Agency). 1976. *Quality Criteria for Water*. Office of Water and Hazardous Materials. Washington, DC. July.

USEPA (U.S. Environmental Protection Agency). 1986a. *Ambient Water Quality Criteria for Bacteria – 1986.* Office of Water Regulations and Standards. Washington, DC. EPA/440/5-84/002. January.

USEPA (U.S. Environmental Protection Agency). 1986b. *Test Methods for Escherichia coli and Enterococci in Water by the Membrane Filter Procedure*. Office of Research and Development. Cincinnati, OH. EPA/600/4-85/076.

USEPA (U.S. Environmental Protection Agency). 1990. *Technical Support Document on Health Risk Assessment of Chemical Mixtures*. Office of Research and Development. Washington, DC. EPA/600/8-90/064. August.

USEPA (U.S. Environmental Protection Agency). 1992. Guidelines for exposure assessment. *Federal Register* 57:22888-22938.

USEPA (U.S. Environmental Protection Agency). 1995. *Policy for Risk Characterization*. Memorandum of Carol M. Browner, Administrator. March 21, 1995. Washington, DC.

USEPA (U.S. Environmental Protection Agency). 1996a. Draft revisions to guidelines for carcinogen risk assessment. *Federal Register* 61:17960.

USEPA (U.S. Environmental Protection Agency). 1996b. Guidelines for reproductive toxicity risk assessment. *Federal Register* 61:6274-56322.

USEPA (U.S. Environmental Protection Agency). 1997. *Method 1600: Membrane Filter Test Method for Enterococci in Water*. Office of Water. Washington, DC. EPA/821/R-97/004. May.

USEPA (U.S. Environmental Protection Agency). 1998a. *Draft Water Quality Criteria Methodology: Human Health*. Office of Water. Washington, DC. EPA-822-Z-98-001. *(Federal Register* 63:43756)

USEPA (U.S. Environmental Protection Agency). 1998b. *Ambient Water Quality Criteria for the Protection of Human Health. Hexachlorobutadiene (HCBD). Draft.* Office of Water. Washington, DC. EPA 882-R-98-004. July.

USEPA (U.S. Environmental Protection Agency). 1999a. *1999 Guidelines for Carcinogen Risk Assessment. Review Draft.* Office of Research and Development. Washington, DC. NCEA-F-0644.

USEPA (U.S. Environmental Protection Agency). 1999b. *Action Plan for Beaches and Recreational Waters. Reducing Exposures to Waterborne Pathogens.* Office of Research and Development and Office of Water. Washington, DC. EPA-600-R-98-079. March.

USEPA (U.S. Environmental Protection Agency). 2000. *Improved Enumeration Methods for the Recreational Water Quality Indicators: Enterococci and Escherichia coli*. Office of Water, Office of Science and Technology. Washington, DC. EPA-821-R-97-004. March.